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Safe dependable vaccines, serums, antitoxins, and other USDA licensed veterinary biologics help maintain healthy herds and flocks to provide the Nation with wholesome meat, eggs, and milk. N-14416



Veterinary Vaccines, Serums, Antitoxins ... Keeping Them Safe and Effective

Advances in veterinary medicine have spurred the development and use of many vaccines, anti-toxins, serums, and other biological materials for the prevention, treatment, and diagnosis of animal diseases. Control of these veterinary biologics to assure that they are safe and effective is an increasingly important U. S. Department of Agriculture protective service.

Although it is designed primarily to help livestock and poultry producers maintain healthy herds and flocks, this service touches all of the Nation's consumers. It helps to provide adequate supplies of wholesome meat, milk, and eggs. It also protects consumers against brucellosis, anthrax, rabies, bovine tuberculosis, and other animal diseases that may be transmitted to humans.

Veterinarians of the Animal Inspection and Quarantine Division of the Agricultural Research Service administer the virus-serum-toxin law which provides this protection. When this law went into effect in 1913, there were only a dozen such products. Now there are over 140 different veterinary biologics. In 1962 USDA veterinary inspectors supervised the production of 4.7 billion doses. Of these, about 185 million doses were destroyed because they were contaminated, or ineffective.

Before USDA grants a license to produce a biologic, Department veterinarians review the manufacturer's outline of production procedures and go over the bibliography of research literature submitted. The veterinarians give special attention to the field trial data given to support the manufacturer's claims and in some instances may test the product in a USDA laboratory. They review trade labels and directions and may require them to be clarified. They

also inspect the laboratory facilities and equipment for production and testing of the product. They aim to make sure that the product is effective, is safe to use, and will not spread animal disease.

After a license has been issued, the manufacturer forwards samples of each serial lot to the Biologics Repository at the National Animal Disease Laboratory at Ames, Iowa, where they may be used for check-testing the assays reported by the licensee.

A USDA veterinary biological inspector is assigned to one or more licensed plants to provide a constant safeguard. He makes periodic inspections of sanitary conditions, observes production and testing in progress, examines records, initiates corrective actions, and reports his findings.

Live virus vaccines which are increasing in number and in volume of production, require constant re-evaluation to assure that they are effective and safe. The magnitude of this task is illustrated by the doubling of the production of Newcastle-bronchitis vaccine for poultry—alone—from 1,560 million doses in 1956 to 3,408 million doses in 1962.

As new processing methods or new tests are developed which will improve the quality of a product, they are applied to all licensed producers. For example, after recent testing of the modified live-virus type of rabies vaccine a shortened expiration date on the vaccines was required to assure potency.

The modern testing and laboratory facilities and staff at the new National Animal Disease Laboratory at Ames, Iowa, now enable USDA regulatory veterinarians to more effectively take the lead in developing the standards needed to insure the purity, potency, and safety of biologics used for animals.



Before licensing a biologic, highly trained USDA veterinarians review production methods, research literature, and field trial data. Trade labels must identify the product and give clear and frank directions for use.

N-47642



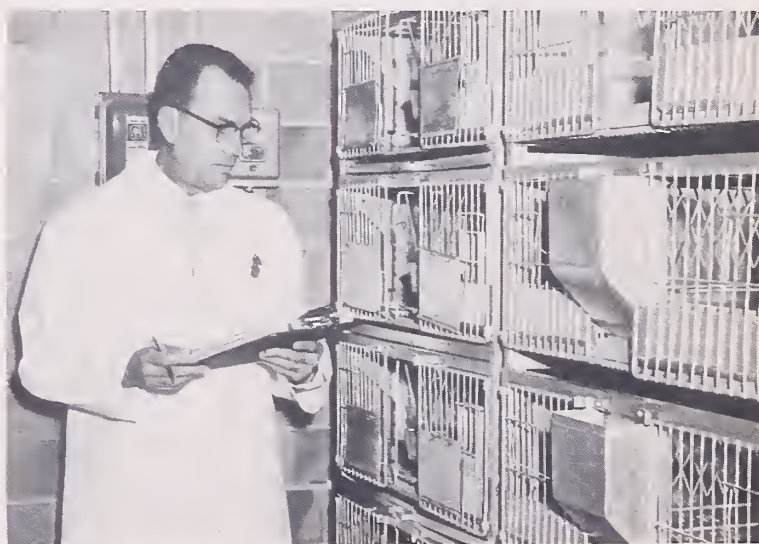
Federal veterinarian at a USDA licensed plant observes handling of viral culture in special hood. He notes identification and dates of bacterial and viral seed cultures used at the plant for starting new batches of veterinary vaccines. N-41128



Chick embryos which have been inoculated with virus are being harvested here for the production of live virus vaccine in a USDA licensed laboratory. N-41116



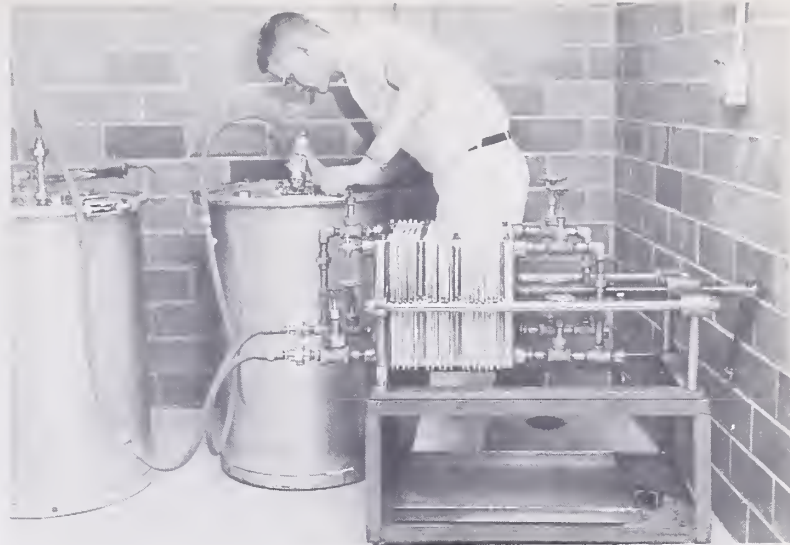
Live virus is inoculated into eggs containing developing chick embryos. The virus grows in the cells and fluids of the embryonic tissues. This method is used in the preparation of several different types of live-virus vaccines. N-41119



Guinea pigs used in testing rabies vaccine are observed and records examined by a USDA veterinarian. The guinea pigs are vaccinated with test rabies vaccine and then injected with virulent rabies virus. If a high percent are not protected against paralysis caused by the rabies virus, the vaccine is considered impotent. N-41125



A rabbit test determines safety of a vaccine for leptospirosis--a disease of cattle. Different laboratory animals are used, depending on the product to be tested. N-41113



Anti-swine-erysipelas serum of equine origin is passed through the special bacterial filter shown here. All facilities and equipment of licensed biological producers must meet high federal standards. N-41106



This healthy USDA-inspected horse is one of many that provide hyperimmune blood needed to produce the life-saving tetanus antitoxin. N-41120



Tuberculin used for the detection of tuberculosis in animals is in preparation here. Technician wearing protective mask and working in an enclosed cubicle inoculates culture media with the bacteria -- a step in the production of the biologic at a USDA inspected plant. N-41107

USDA veterinarian inspects baby chicks used in checking safety of live virus vaccines recommended for young birds. BN-12222X





Dependable hog-cholera vaccine produced under USDA license and inspection provides effective protection against the disease. 80904-B

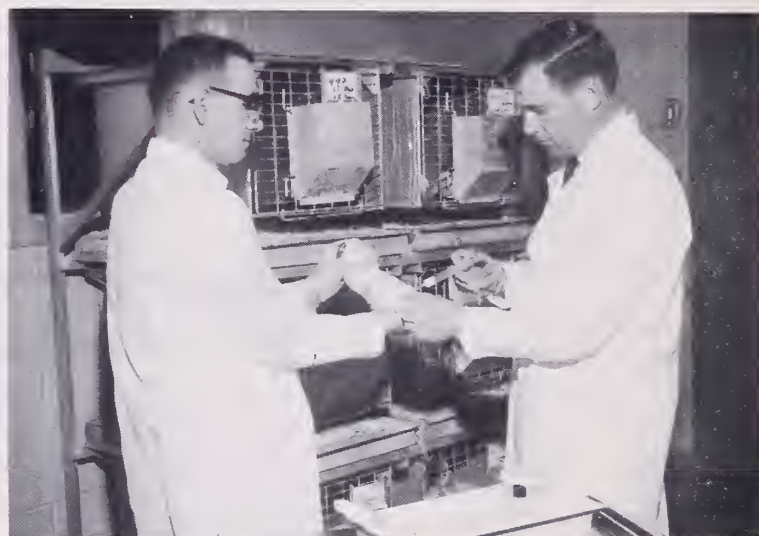


Brucella abortus vaccine is an important aid in the program to eradicate brucellosis from cattle. In 1962, one out of every 8 doses produced--enough to vaccinate over 1 million young animals--was found unsatisfactory and kept off the market by USDA biologics veterinarians. N-37936

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USDA veterinarian observes test of distemper vaccine on puppy at a USDA licensed laboratory. N-41129



Testing and standardizing the growing number of veterinary biologics is now possible at the new National Animal Disease Laboratory at Ames, Iowa. Here a commercially produced modified live virus vaccine is being tested on a guinea pig. N-46073



Certain foreign animal-disease organisms and vectors for research studies are received and transported in this country under permit and supervision by USDA biologics veterinarians. Some organisms and vectors, because of the danger involved, are prohibited. Here a customs officer turns over to a USDA inspector a package containing culture organisms brought from abroad. N-38283